OCTOBER 2014 • VOLUME 14-07
PHARMACISTS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

Nova Scotia Formulary Updates

New Exception Status Benefits

The following products will be listed with the following criteria effective October 31, 2014.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Esbriet® (pirfenidone)	267mg Cap	02393751	DNP	E	ITM

Criteria

Initial approval criteria:

- Adult patients who have a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF) [1] confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
- Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)

Initial renewal criteria:

- Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.
- Approval period: 6 months

[1] Mild-moderate IPF is defined as: a FVC between 50-80% predicted, and a Percent Carbon Monoxide Diffusing Capacity (%DLCO) between 30-90% predicted.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Esbriet® (pirfenidone)	267mg Cap	02393751	DNP	E	ITM
Criteria	Second renewal criteria (12 months after initiation of therapy): • Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% since initiation of therapy (baseline). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later • Approval period: 12 months				
Decision Highlights	• The Canadian Drug Expert Committee will be reviewing new clinical evidence available for the use of pirfenidone which may result in a change in benefit status.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Mozobil® (plerixafor)	24mg/1.2mL (20mg/mL) Single Use Vial	02377225	DNP	E	SAV
Criteria	• For use in combination with filgrastim to mobilize hematopoietic stem cells for subsequent autologous transplantation in patients with Non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM) if one of the following criteria are met: o a PBCD34+ count of < 10cells/uL after 4 days of filgrastim; OR o less than 50% of the target CD34 yield is achieved on the 1st day of apheresis (after being mobilized with filgrastim alone or following chemotherapy); OR o if a patient has failed a previous stem cell mobilization with filgrastim alone or following chemotherapy. Notes: • Reimbursement is limited to a maximum of 4 doses (0.24mg/kg given daily) for a single mobilization attempt and to prescriptions written by an oncologist or hematologist.				

New Exception Status Benefits Continued...

The following product has been reviewed by the Canadian Drug Expert Committee (CDEC) and will be listed as an exception status benefit, with the following criteria effective October 31, 2014.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tudorza® Genuair® (aclidinium bromide)	400mcg Powder for Inhalation	02409720	DNP	E	ALM
Criteria	• For the treatment of chronic obstructive pulmonary disease (COPD), if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e., salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day) • Coverage can be provided without a trial of short-acting agent if: o there is spirometric evidence of at least moderate to severe airflow obstruction (i.e., postbronchodilator values FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms (i.e., MRC score pf 3-5[1]) • Combination therapy with aclidinium bromide and a long-acting beta2 agonist/inhaled corticosteroid will only be considered if: o there is spirometric evidence of at least moderate to severe airflow obstruction (postbronchodilator values FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms (i.e., MRC score of 3-5[1]); AND o there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids				

[1] Canadian Thoracic Society COPD Classification By Symptom/Disability:

Moderate - (MRC 3-4) Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.

Severe - (MRC 5) Shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

MRC= Medical Research Council Dyspnea Scale

Criteria Update

The following product was reviewed by the Canadian Drug Expert Committee (CDEC) and will be listed with the following new criteria effective October 31, 2014.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xarelto® (rivaroxaban)	15mg Tab 20mg Tab	02378604 02378612	DNP DNP	E E	BAY BAY
Criteria	• For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) • Approval Period: Up to six (6) months • Criteria Code 42 will be used to allow the 15mg strength to pay (max 42 tablets), which will allow patients to start therapy while awaiting ESD approval for the six months of therapy Notes: • The recommended dose of rivaroxaban for patients initiating DVT or PE treatment is 15mg twice daily for 3 weeks, followed by 20mg once daily • Drug Plan coverage for rivaroxaban is an alternative to heparin/warfarin for up to six months. When used for greater than 6 months, rivaroxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin • Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risk should be assessed and monitored (see product monograph).				
Decision Highlights	• In the EINSTEIN PE trial, rivaroxaban was reported to be non-inferior to a regimen of enoxaparin plus warfarin. Based on a cost minimization analysis, rivaroxaban is less costly than enoxaparin plus warfarin when treating patients for up to six months. Therefore coverage criteria for the treatment of venous thrombotic events has been expanded to include patients with pulmonary embolism. Note that coverage is limited to six months, therefore, patients who have a likely treatment duration of greater than six months should be considered for initiation of heparin/warfarin.				

New Product

The following product is a new listing to the Nova Scotia Formulary, effective October 31, 2014. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lodalis® (colesevelam)	625mg Tab	02373955	DNP	SF	VLN